



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Athenex, Inc. (“Athenex”) headquartered in Buffalo, NY.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to:

Suna Gulay French, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5530; E-mail: suna.gulay@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

GROUP A:

E-237-2017-0/2: T Cell Receptors Recognizing Mutated P53

1. US Provisional Patent Application 62/565,383, filed September 29, 2017 (E-237-2017-0-US-01);
2. International Patent Application PCT/US2018/051285, filed September 17, 2018 (E-237-2017-2-PCT-01);
3. Australian Patent Application 2018342246, filed September 17, 2018 (E-237-

- 2017-2-AU-02);
4. Brazilian Patent Application BR112020006012-7, filed September 17, 2018 (E-237-2017-2-BR-03);
 5. Canadian Patent Application 3077024, filed September 17, 2018 (E-237-2017-2-CA-04);
 6. Chinese Patent Application 201880074539.8, filed September 17, 2018 (E-237-2017-2-CN-05);
 7. Costa Rica Patent Application 2020-0170, filed September 17, 2018 (E-237-2017-2-CR-06);
 8. Eurasian Patent Application 202090757, filed September 17, 2018 (E-237-2017-2-EA-07);
 9. European Patent Application 18780006.5, filed September 17, 2018 (E-237-2017-2-EP-08);
 10. Israeli Patent Application 273515, filed September 17, 2018 (E-237-2017-2-IL-09);
 11. India Patent Application 202047013911, filed September 17, 2018 (E-237-2017-2-IN-10);
 12. Japanese Patent Application 2020-517556, filed September 17, 2018 (E-237-2017-2-JP-11);
 13. Korean Patent Application 2020-7012344, filed September 17, 2018 (E-237-2017-2-KR-12);
 14. Mexico Patent Application MX/a/2020/003504, filed September 17, 2018 (E-237-2017-2-MX-13);
 15. New Zealand Patent Application 763023, filed September 17, 2018 (E-237-2017-2-NZ-14);
 16. Singapore Patent Application 11202002636P, filed September 17, 2018 (E-237-2017-2-SG-15);
 17. United States Utility Patent Application 16/651,242, filed September 17, 2018 (E-237-2017-2-US-16); and
 18. Hong Kong Patent Application 62020021272.3, filed November 30, 2020 (E-237-2017-2-HK-17).

E-135-2019: T Cell Receptors Recognizing R175H Or Y220C Mutation in P53

1. US Provisional Patent Application 62/867,619, filed June 27, 2019 (E-135-2019-0-US-01);
2. International Patent Application PCT/US2020/039785, filed June 26, 2020 (E-135-2019-0-PCT-02); and
3. Taiwanese Patent Application 109121744, filed June 26, 2020 (E-135-2019-0-TW-03).

E-173-2020: T Cell Receptors Recognizing R273C Or Y220C Mutation in P53

1. US Provisional Patent Application 63/074,747, filed September 4, 2020 (E-173-2020-0-US-01).

E-098-2018: T Cell Receptors Which Recognize Mutated EGFR

1. US Provisional Patent Application 62/665,234, filed May 1, 2018 (E-098-2018-0-US-01);
2. International Patent Application PCT/US2019/030108, filed May 1, 2019 (E-098-2018-0-PCT-02);
3. Australian Patent Application 2019263233, filed May 1, 2019 (E-098-2018-0-AU-03);
4. Canadian Patent Application 3,099,106, filed May 1, 2019 (E-098-2018-0-CA-04);

5. European Patent Application 19723615.1, filed May 1, 2019 (E-098-2018-0-EP-05); and
6. United States Utility Patent Application 17/051,860, filed May 1, 2019 (E-098-2018-0-US-06).

E-165-2020: HLA Class II-Restricted DRB T Cell Receptors Against RAS with G12D Mutation

1. US Provisional Application 63/050,931, filed July 13, 2020 (E-165-2020-0-US-01).

E-172-2020: HLA Class II-Restricted DRB T Cell Receptors Against RAS with G12V Mutation

1. US Provisional Application 63/052,502, filed July 16, 2020 (E-172-2020-0-US-01).

E-189-2020: HLA Class II-Restricted DQ T Cell Receptors Against RAS with G13D Mutation

1. US Provisional Application 63/086,674, filed October 2, 2020 (E-189-2020-0-US-01).

E-190-2020: HLA Class I-Restricted T Cell Receptors Against RAS with G12V Mutation

1. US Provisional Application 63/060,340, filed August 3, 2020 (E-190-2020-0-US-01).

GROUP B:

E-237-2017-1: Methods of Isolating T Cells Having Antigenic Specificity for a P53 Cancer-Specific Mutation

1. US Provisional Patent Application 62/565,464, filed September 29, 2017 (E-237-2017-1-US-01);
2. International Patent Application PCT/US2018/051280, filed September 17, 2018 (E-237-2017-1-PCT-02);
3. Australian Patent Application 2018342245, filed September 17, 2018 (E-237-2017-1-AU-03);
4. Canadian Patent Application 3080274, filed September 17, 2018 (E-237-2017-1-CA-04);
5. Chinese Patent Application 201880063656.4, filed September 17, 2018 (E-237-2017-1-CN-05);
6. European Patent Application 18782605.2, filed September 17, 2018 (E-237-2017-1-EP-06);
7. Israeli Patent Application 273516, filed September 17, 2018 (E-237-2017-1-IL-07);
8. Japanese Patent Application 2020-517553, filed September 17, 2018 (E-237-2017-1-JP-08);
9. Korean Patent Application 2020-7012343, filed September 17, 2018 (E-237-2017-1-KR-09);
10. Singapore Patent Application 11202002635R, filed September 17, 2018 (E-237-2017-1-SG-10);
11. United States Utility Patent Application 16/650,696, filed September 17, 2018 (E-237-2017-1-US-11); and
12. Hong Kong Patent Application 62020021274.9, filed November 30, 2020 (E-237-2017-1-HK-12).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

FIELDS OF USE APPLYING TO INTELLECTUAL PROPERTY GROUP A

“Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered via retrovirus and lentivirus-mediated gene transfer to express T cell receptors reactive to mutated p53, KRAS and EGFR within the context of multiple HLAs, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are, (a) transposon-engineered peripheral blood T cell therapy products for the treatment of human cancers, and (b) CRISPR-engineered peripheral blood T cell therapy products for the treatment of human cancers.

Development, manufacture, and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.”

FIELDS OF USE APPLYING TO INTELLECTUAL PROPERTY GROUP B

“Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered via retrovirus and lentivirus-mediated gene transfer to express T cell receptors reactive to mutated P53, isolated as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are, (a) transposon-engineered peripheral blood T cell therapy products for the treatment of human cancers, and (b) CRISPR-engineered peripheral blood T cell therapy products for the treatment of human cancers.

Development, manufacture, and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.”

Intellectual Property Group A description is as follows:

E-237-2017-0, E-135-2019 and E-173-2020 patent rights are primarily directed to isolated TCRs reactive to mutated tumor protein 53 (TP53 or P53), within the context of several HLAs. *P53* is the archetypal tumor suppressor gene and the most frequently mutated gene in cancer. Contemporary estimates suggest that >50% of all tumors carry mutations in *P53*. Because of its prevalence in cancer and its restricted expression to precancerous and cancerous cells, this antigen may be targeted on mutant P53-expressing tumors with minimal normal tissue toxicity.

E-165-2020, E-172-2020, E-189-2020 and E-190-2020 patent rights are primarily directed to isolated TCRs reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including: pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.

E-098-2018 patent rights are primarily directed to isolated TCRs reactive to mutated epidermal growth factor receptor (EGFR), within the context of HLA DPA1*02:01 DPB1*01:01. EGFR is a transmembrane protein involved in cell growth and proliferation signaling. Mutations in the gene encoding EGFR can lead to its overexpression, causing several types of cancer (*e.g.*, non-small cell lung cancer (NSCLC)). Because of its prevalence in certain cancers and its restricted expression to

precancerous and cancerous tissues, this antigen may be targeted on mutant EGFR-expressing tumors with minimal normal tissue toxicity.

Intellectual Property Group B description is as follows:

E-237-2017-1 patent rights are primarily directed to methods of rapidly isolating T cells which are reactive to mutated P53 antigens. Briefly, pools of 25-mer peptides covering all known P53 “hotspot” mutations have been generated. These peptides may be pulsed into autologous antigen presenting cells which are subsequently co-cultured with the patient’s isolated T cells. Reactive T cells are then purified and may be used as source material for the further isolation of mutant P53-targeting TCRs.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

April 21, 2021.

Dated

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.

